DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

ORIGINAL

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

July 2, 2003

EX PARTE OR LATE FILED

Ms. Marlene H. Dortch
Secretary
Federal Communications Commission
445 12th Street, S.W., Room TW-A325
Washington, DC 20554

RE: Section 68.4(a) of the Commission's Rules Governing
Hearing Aid-Compatible Telephones
WT Docket No. 01-309 **EX PARTE**

Dear Ms. Dortch:

On behalf of the Food and Drug Administration (FDA), Center for Devices and Radiological Health, I would like to respond to the April 18, 2003, and March 26, 2003, submissions of the Hearing Industries Association (HIA) concerning hearing aid labeling for compatibility with digital wireless phones.

In its submissions, HIA expresses concern about the ability of hearing aid manufacturers to label or advertise hearing aids with claims about their immunity to interference when used with digital wireless telephones. In their March 26, 2003, letter, HIA states that "FDA regulations require any label claiming a certain performance characteristic for a hearing aid must be justified by compliance by a very high threshold of units manufactured." In their April 18, 2003, submission, HIA asserts that claims must be supported by studies, the results of which must be retained by the manufacturer and produced if ordered by the FDA. HIA states its belief that "very little leeway is permitted for failure to meet claims for medical devices, because of the potentially serious consequences to health if an individual unit of any medical device does not meet a claim." HIA relies on a 1994 FDA publication, "Guidance to Hearing Aid Manufacturers for Substantiation of Claims," which contains guidelines for the conduct of studies and the resulting information from those studies that is appropriate for labeling. (We note that this guidance document pre-dates the down classification of air conduction hearing aids from Class II to Class I devices, which occurred on January 14, 2000, and that the above noted guidance document was withdrawn on April 14, 2000.)

In the context of the Commission's proceeding on the compatibility of hearing aids and digital wireless telephones, we understand it would be useful for hearing aid manufacturers to test and label hearing aid models with their performance category based on the ANSI C63.19-2001 standard. The ANSI C63.19 standard was published through the ANSI consensus standards-setting process, and is recognized by FDA as a standard that manufacturers and the agency may use as part of the regulatory process for hearing aid devices. This standard contains a methodology for categorizing hearing aids from U1 (least immune) to U4 (highest specified level of immunity) based on their immunity to interference from wireless devices such as cellular telephones. The ANSI standard is also used to rate the immunity to interference of digital wireless phones. Hearing aid labeling based on the ANSI standard would facilitate consumer selection of a hearing aid and digital wireless phone that should work properly together

HIA is concerned that while the manufacturers labeling of a hearing aid may accurately reflect the ANSI rating at manufacture, the labeling does not address ratings when these devices are customized or adjusted by practitioners. HIA has indicated that, while most new hearing aid models perform at the U2 level, only 80 to 85 percent of hearing aids consistently meet the U2 level after customization for a particular user. Although hearing aid manufacturers can correct problems after initial delivery, HIA expresses concern that a label affixed prior to individual adjustment would risk misbranding under FDA regulations if a given hearing aid did not work with a particular wireless phone.

While the FDA expects manufacturers of medical devices to have data to support any claims about product performance made on labels or as part of the advertising of those devices, we take this opportunity to clarify the FDA's policy with respect to substantiation of the type of performance claims you have addressed for the conformance of hearing aids to this technical ANSI standard. These claims about hearing aid performance may be supported by bench or laboratory tests, and no user studies are necessary. The ANSI standard was devised and is intended to be applied through that type of non-clinical testing. In these circumstances, labeling hearing aid models with a statement that the unadjusted aid meets a particular ANSI immunity level would not violate FDA requirements. For example, if a given hearing aid model achieves a U2 category based on standardized laboratory tests that are in conformance with the ANSI standard, FDA would not take enforcement action against a product that conveyed that information on the label. Nor would FDA have concerns about an assertion on the label of a hearing aid that individual hearing aid users will have varying results with cell phones.

The FDA looks forward to partnering with the FCC on public education efforts to inform users of hearing aids, the medical and audiological communities, manufacturers of hearing aid devices, and other consumers about the FCC's efforts to make hearing aid-compatible wireless phones more readily available to consumers. These efforts may include information about potential changes in immunity performance levels that follow customization or adjustment of individual hearing aids.

We hope this submission assists in clarifying the FDA position on hearing aid labeling. Although this written communication is an exempt ex parte presentation under the Commission's rules, 47 C.F.R. § 1.204(a)(5), we submit this letter in the public docket for the Commission's consideration in this proceeding.

If you have any question regarding this matter, please contact me at 301-594-4692.

Sincerely yours,

Harold A. Pellerite
Assistant to the Director
Office of Compliance
Center for Devices and
Radiological Health